



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,150	07/17/2003	Robert W. Childers	3712044-00440	5656
29200 K&L Gates LLP P.O. Box 1135 Chicago, IL 60690-1135	7590 07/22/2010			
EXAMINER				
SCHELL, LAURA C				
ART UNIT		PAPER NUMBER		
3767				
NOTIFICATION DATE		DELIVERY MODE		
07/22/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

### Office Action Summary

**Application No.**

10/624,150

**Applicant(s)**

CHILDERS ET AL.

**Examiner**

LAURA C. SCHELL

**Art Unit**

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saki (US Patent No. 6,666,842) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Saki discloses the system substantially as claimed including a system for providing peritoneal dialysis to a patient (Fig. 1 for example) comprising: a catheter having an inflow lumen and an outflow lumen in communication with the patient's peritoneal cavity (col. 4, lines 45-46 disclose that a double lumen catheter may be used); and a fluid circuit in fluid communication with the catheter the fluid circuit comprising: a fluid loop (Fig. 1 discloses the fluid loop), the fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient (1), a supply of a dialysate coupled to the fluid circuit (14), and at least

one of a chamber coupled to the fluid loop through which the dialysate can be fed at a feed rate into the fluid loop (the chamber can be interpreted as either the chamber 14 in which the supply of dialysate resides or it can be interpreted as a portion of the fluid line connecting 14 with the fluid loop as no other structure regarding the chamber is currently being claimed; pump 13 feeds the dialysate into the fluid loop at a feed rate), and a cleaning device (filter 10/11) coupled to the fluid loop via a cleaning fluid path wherein the dialysate can be fed into the cleaning fluid path and cleaned at a cleaning rate prior to reintroduction into the fluid loop (the cleaning path is being interpreted as the path the fluid flow when it exits pump 9, enters the filter 10/11 and then exits the cleaning path when it hits pump 16, the rate at which the fluid flows through this path can be interpreted as the cleaning rate); a discharge fluid path coupled to the fluid loop (discharge fluid path is the path which contains pump 12 which is connected to 10); and a cyclor that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove a therapeutic effective amount of solutes and excess water from the patient, the cyclor further configured to drain the dialysate from the fluid circuit (Fig. 1 discloses the that fluid circuit's cyclor is made up of several different pumps: pump 9 which can be used for generally pumping the fluid circuit as the pumping action would both draw fluid out of the patient and pump fluid into the cleaning loop; pump 12 can be used to pump fluid through the discharge fluid path; pump 13 can be used for pumping fluid from the supply and into the fluid loop; pump 16's pumping action would both draw fluid out of the cleaning loop as well as pump fluid into the patient). Saki, however, does not disclose the specific flow rates

such as the outflow rate from the peritoneal cavity being greater than the inflow rate, the discharge rate being less than the circulation rate and substantially equal to a difference between the outflow rate and the inflow rate, and the rates allowing the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. Roberts, however, discloses Roberts, however, discloses a fluid loop in which the fluid is drained at a rate less than the circulation rate thus allowing the fluid to circulate a plurality of times along the fluid loop prior to being drained (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. This paragraph also corresponds to the second paragraph in the second column of page 374 in which circulation rates and inflow/outflow rates are disclosed.). Roberts, while not teaching the exact rates claimed by Applicant, does teach that it is well known in the art to use different drainage and circulation rates in the system in order to cause the dialysate to cycle around the fluid loop a plurality of times prior to discharge. It is therefore obvious to one of ordinary skill in the art at the time of the invention to have used the teachings of Roberts to modify and adjust the fluid rates within Saki in order to cause the dialysate to circulate along the fluid loop a plurality of times before discharge, as this would only involve adjusting flow rates to desired rates to produce the desired number of circulation loops of the dialysate, and it has been held that discovering an

optimum value of a result effective variable involves only routine skill in the art. Furthermore, Saki's fluid circuit possesses multiple pumps along many different sections of the fluid loop and is therefore very capable of having each pump adjusted to a different flow rate to produce the desired flow rates and the resulting circulation of the dialysate along the fluid loop multiple times.

In reference to claim 5, Saki discloses that the cyclor comprises two pumps (there are multiple pumps disclosed in Saki (9, 12, 13, 16 as well as 15)).

In reference to claim 8, Saki discloses that the cleaning device contains at least one electrolyte for addition to the dialysate (col. 5, lines 15-16).

In reference to claim 9, Saki discloses that the cleaning device contains at least three layers (Fig. 1 discloses that the filter has three layers).

In reference to claim 10, Saki discloses the chamber allowing the fluid loop to accommodate a variable increase in the dialysate during treatment (container 17a can be used to accumulate fluid as well).

In reference to claim 11, Roberts discloses that the increase is due to an addition of ultrafiltrate to the fluid loop (paragraph 2, col. 2 of page 374).

In reference to claim 12, Saki discloses at least one valve connecting the catheter to the fluid circuit (valve 4 for example).

Claims 13, 14, 16-20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saki (US Patent No. 6,666,842) in view of Roberts et al. ("Innovative

Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Saki discloses the system substantially as claimed including a system for providing peritoneal dialysis to a patient (Fig. 1 for example) comprising: a catheter having an inflow lumen and an outflow lumen in communication with the patient's peritoneal cavity (col. 4, lines 45-46 disclose that a double lumen catheter may be used); and a fluid circuit in fluid communication with the catheter the fluid circuit comprising: a fluid loop (Fig. 1 discloses the fluid loop), the fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient (1) via only a single loop of the fluid loop (Fig. 1 discloses that the fluid circuit is comprised of a single fluid loop (section including pump 15 and container 17a is named the recirculation circuit and col. 6, lines 64-67 disclose that the fluid flows through this circuit only if needed, therefore indicating that this portion of the circuit does not need to be used), the fluid loop including a first fluid line in communication with a dialysate supply (fluid line between supply 14 and filter 10/11), a second fluid line in communication with a discharge fluid path (fluid line containing discharge pump 12), a third line in communication with an outflow fluid path from the peritoneal cavity (fluid line leading up to pump 9), and a fourth fluid line in communication with an inflow fluid path to the peritoneal cavity fluid line between 16 and 22); a supply of dialysate (14), and a chamber coupled to the fluid loop through which the dialysate can be fed at a feed rate into the fluid loop (the chamber can be interpreted as either the chamber 14 in which the supply of dialysate resides or it can be interpreted as a portion of the fluid line connecting 14 with the fluid loop as no other structure regarding the chamber is currently being claimed; pump 13 feeds the dialysate into the fluid loop at a feed rate);

and a cyclor that pumps the dialysate into the fluid loop and circulates the dialysate along the fluid loop at a circulation rate to remove a therapeutic effective amount of solutes and excess water from the patient (the cyclor includes various pumps including pump 9 which can be used for generally pumping the fluid circuit as the pumping action would both draw fluid out of the patient and pump fluid into the cleaning loop; pump 12 can be used to pump fluid through the discharge fluid path; pump 13 can be used for pumping fluid from the supply and into the fluid loop; pump 16's pumping action would both draw fluid out of the cleaning loop as well as pump fluid into the patient); and wherein the discharge fluid path is coupled to the second and third fluid lines through which the dialysate is drained from the fluid circuit (the discharge fluid path is coupled to the second fluid line which leads to the discharge fluid path and is also coupled to the third fluid line via its connection to the filter). Roberts, while not teaching the exact rates claimed by Applicant, does teach that it is well known in the art to use different drainage and circulation rates in the system in order to cause the dialysate to cycle around the fluid loop a plurality of times prior to discharge. It is therefore obvious to one of ordinary skill in the art at the time of the invention to have used the teachings of Roberts to modify and adjust the fluid rates within Saki in order to cause the dialysate to circulate along the fluid loop a plurality of times before discharge, as this would only involve adjusting flow rates to desired rates to produce the desired number of circulation loops of the dialysate, and it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. Furthermore, Saki's fluid circuit possesses multiple pumps along many different sections of the fluid loop and is



therefore very capable of having each pump adjusted to a different flow rate to produce the desired flow rates and the resulting circulation of the dialysate along the fluid loop multiple times.

In reference to claim 14, Roberts discloses that the supply of dialysate contains about 25 liters or less of dialysate (Fig. 12, which is circuit that modified circuit of paragraph 2 is based on, uses 20 L of dialysate, which is less than 25 L).

In reference to claim 16, Roberts discloses that the circulation rate is about 300 ml/min or less (Roberts discloses in paragraph 1, col. 1 on page 377, the unmodified circuit in Fig. 12 uses a rate of 200 ml/min which is less than 300. Also, paragraph 2, col. 1, page 377 discloses using a rate of 200 ml/min):

In reference to claim 17, Roberts discloses that the chamber is capable of mixing and heating the dialysate (Fig. 7 and 12, specifically Fig. 12 discloses a heater).

In reference to claim 18, Saki discloses that the chamber is coupled to the fluid loop via a fluid supply path (path connecting 14 to the filter/loop).

In reference to claim 19, Roberts discloses that the feed rate and the discharge rate are less than the circulation rate (paragraph 2, col. 1, page 377 discloses using inflow and outflow rates of 30 ml/min while using a higher circulation rate. Also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using a circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged).

In reference to claim 20, Saki discloses that the chamber is directly coupled to the fluid loop (Fig. 1 discloses that 14 is directly coupled to the fluid loop).

In reference to claim 22, Roberts discloses that the dialysate is continuously fled, circulated and drained over a treatment period of about 8 hours or less (paragraph 2, col. 1, page 377 discloses the fluid circuit referenced in claim 1, which is based off of the circuit in the paragraph above, which teaches an 8 hour treatment).

In reference to claim 23, Saki discloses the chamber allowing the fluid loop to accommodate a variable increase in the dialysate during treatment (container 17a can be used to accumulate fluid as well).

Claims 24-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saki (US Patent No. 6,666,842) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Saki discloses the system substantially as claimed including a system for providing peritoneal dialysis to a patient (Fig. 1 for example) comprising: a catheter having an inflow lumen and an outflow lumen in communication with the patient's peritoneal cavity (col. 4, lines 45-46 disclose that a double lumen catheter may be used); and a fluid circuit in fluid communication with the catheter thereby defining only a single fluid loop (section including pump 15 and container 17a is named the recirculation circuit and col. 6, lines 64-67 disclose that the fluid flows through this circuit only if needed, therefore indicating that this portion of the circuit does not need to be used) capable of circulating dialysate into, through and out of the peritoneal cavity, the fluid circuit comprising: a supply of a dialysate coupled to the fluid loop (14), a cleaning device (filter 10/11) coupled to the fluid loop via a cleaning

fluid path wherein the dialysate can be fed into the cleaning fluid path and cleaned at a cleaning rate prior to reintroduction into the fluid loop (the cleaning path is being interpreted as the path the fluid flow when it exits pump 9, enters the filter 10/11 and then exits the cleaning path when it hits pump 16, the rate at which the fluid flows through this path can be interpreted as the cleaning rate); a discharge fluid path coupled to the fluid loop (discharge fluid path is the path which contains pump 12 which is connected to 10); and a cyclor that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove a therapeutic effective amount of solutes and excess water from the patient, the cyclor further configured to drain the dialysate from the fluid circuit (Fig. 1 discloses the that fluid circuit's cyclor is made up of several different pumps: pump 9 which can be used for generally pumping the fluid circuit as the pumping action would both draw fluid out of the patient and pump fluid into the cleaning loop; pump 12 can be used to pump fluid through the discharge fluid path; pump 13 can be used for pumping fluid from the supply and into the fluid loop; pump 16's pumping action would both draw fluid out of the cleaning loop as well as pump fluid into the patient). Saki, however, does not disclose the specific flow rates such as the outflow rate from the peritoneal cavity being greater than the inflow rate, the discharge rate being less than the circulation rate and substantially equal to a difference between the outflow rate and the inflow rate, and the rates allowing the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. Roberts, however, discloses Roberts, however, discloses a fluid loop in which the fluid is drained at a rate less than the circulation rate thus allowing the fluid to

circulate a plurality of times along the fluid loop prior to being drained (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. This paragraph also corresponds to the second paragraph in the second column of page 374 in which circulation rates and inflow/outflow rates are disclosed.). Roberts, while not teaching the exact rates claimed by Applicant, does teach that it is well known in the art to use different drainage and circulation rates in the system in order to cause the dialysate to cycle around the fluid loop a plurality of times prior to discharge. It is therefore obvious to one of ordinary skill in the art at the time of the invention to have used the teachings of Roberts to modify and adjust the fluid rates within Saki in order to cause the dialysate to circulate along the fluid loop a plurality of times before discharge, as this would only involve adjusting flow rates to desired rates to produce the desired number of circulation loops of the dialysate, and it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. Furthermore, Saki's fluid circuit possesses multiple pumps along many different sections of the fluid loop and is therefore very capable of having each pump adjusted to a different flow rate to produce the desired flow rates and the resulting circulation of the dialysate along the fluid loop multiple times.

In reference to claim 25, Saki discloses that the fluid loop is coupled to the supply of dialysate, the cleaning fluid path and the discharge fluid path via a cyclor (Fig. 1).

In reference to claim 26, Saki discloses that the cyclor includes a fluid circuit coupled to a pumping mechanism and a plurality of valves such that the cyclor is capable of automatically controlling the flow of dialysate into and out of the fluid loop during treatment (Fig. 1 discloses several valves (9, 12, 13 and 16) and discloses multiple valves (4 and 24)).

In reference to claims, 27, 28 and 30, Roberts discloses that the cleaning device contains a sorbent material (Fig. 6 discloses using a sorbent cartridge) capable of non-selective removal of solutes from the dialysate prior to reuse and that the sorbent material is carbon (col. 1, paragraph 3, line 1).

Claim 3, 4, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai (US Patent No. 6,666,842) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Sakai in view of Roberts discloses the device substantially as claimed including Roberts disclosing that the feed rate and the discharge rates being lower than the circulation rate (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as

using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. These rates of 200 and 36 are from the same researcher (Kraus et al.) that is being quoted in the second paragraph of col. 1, page 377). Roberts however, does not disclose that the feed and discharge rates are maintained equally at a rate that is either one-half or one-third of the circulation rate, such that the dialysate circulates either two or three times along the fluid loop. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Roberts such that the feed and discharge rates are either one-half or one-third the circulation rate, because it is a mere manipulation or arithmetic in order to derive a circulation of two or three times around the loop, and because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Sakai discloses the device substantially as claimed except for the dialysate being contained in four separate containers each having a capacity of about 6 liters or less. Roberts, however, discloses two different dialysis set ups in which there are multiple containers each with a capacity of 6L or less (Fig. 1 and Fig. 3). While these setups do not disclose four dialysate containers, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Sakai in view of Roberts with extra dialysate containers, since it has been held that mere duplication

of the essential working parts of a device involves only routine skill in the art and it allows the therapy to be customized to the patient depending on how much dialysate is needed for each individual case.

Claims 2, 6, 7 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai (US Patent No. 6,666,842) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration") and further in view of Treu et al. (US Patent No. 6,254,567). Sakai in view of Roberts discloses the device substantially as claimed except for pressure sensors, the cleaning device containing sorbents or an ion exchange resin. Treu, however, discloses a similar peritoneal dialysis system and discloses pressure sensors (76, 78), that the cleaning device contains sorbents for adsorbing at least one of urea, phosphate and creatinine (col. 1 lines 25-26 disclose that the waste products removed by the cleaning device include urea and creatinine) and contains an ion exchange resin (col. 1, line 24). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Sakai in view of Roberts to include a pressure sensor and sorbents and ion exchange resin in the cleaning device, in order to provide a better functioning device.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection. Applicant's amendments to the independent claims necessitated a new primary reference (Sakai), however it is still the

examiner's position that the Roberts reference teaches that it would be obvious to modify flow rates to achieve a desired number of circulation loops/passes of the dialysate around the fluid circuit, which is described above.

Applicant argues that Roberts is not an applicable reference as it teaches circulating fluid multiple times around the loop due to the inflow and outflow rates being equal to each other. Applicant argues that this is different from what is currently being claimed. While the examiner agrees that Roberts teaches setting the inflow and outflow rates being equal to each other to circulate the fluid multiple times around the loop, it is the examiner's position that Roberts teaches the idea of varying flow rates within a fluid loop in order to achieve multiple passes of fluid around the loop. And it would have been obvious to one of ordinary skill in the art to use this teaching from Roberts to have experimented with changing flow rates until the optimal flow rates had been found, as discovering an optimum value of a result effective variable involves only routine skill in the art. Therefore it is the examiner's position that Roberts should be maintained as a secondary reference.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/  
Examiner, Art Unit 3767  
/KEVIN C. SIRMONS/  
Supervisory Patent Examiner, Art Unit 3767